REMARKS/ARGUMENTS

This preliminary amendment is filed to address arguments made in a January 14, 2004 telephone interview with Examiner Portner in the parent case made after filing of the Notice of Appeal and an Amendment after final. In that interview, the Examiner stated that the amendment would not be entered, and raised what Applicants considered to be new issues relating to definiteness. The Examiner also stated that she would provide a detailed advisory action, explaining both the meaning of the rejections, and why she considered the concerns expressed in the interview to be within the scope of this rejection. As of the date of this filing, no Advisory Action has been received. Accordingly, to avoid payment of unnecessary extension fees, Applicants are filing this continuation application, with claims amended as discussed in the interview to address the Examiner's issues to the extent they could be understood without the written statement.

In the parent case, the Examiner rejected claims similar to claims 18-37 under 35 USC § 112, second paragraph as indefinite, citing several bases for the rejection. Each of these bases is addressed below.

Applicants would point out, however, that the standard for definiteness is whether a person skilled in the art, having read the specification, can determine the scope of the claims. The Examiner's statement that "all forms of gonadotropom (sic) are not representative of a menopausal condition" is not relevant, because these forms are not being claimed. What is being claimed is a test methodology where a gonadotropin is tested that has forms that **are** indicative of the menopausal state.

The Examiner appeared in the interview to be confused as to where in the first and second assays, the differences were found. While Applicants do not believe that any person skilled in the art could have experienced the confusion of the Examiner, claim 18 presented herein expressly spells out that which was implicit in the claim in the parent case. No change of scope results from this change. In addition, the final step has been made more generic, and claims 31 and 32 have been added to recite the specific case referenced on page 5, lines 3-7 of the application, stating that the assays "can be modulated such that in a non-menopausal state both assays give rise to a similar signal in terms of a particular colour or colour intensity, whereas in a menopausal state the second assay produces a discernably different colour or colour intensity." The reverse modulation is equally valid, such that a similarity in assay result indicates one state and a difference indicates the other. Thus, the generic scope of claim 18.

In the parent case, the Examiner asserted that claims corresponding to claims 23 and 28 were indefinite because of the references to a ratio. Applicants respectfully traverse this rejection. In response to the Examiner's first inquiry, it does not matter which number is the numerator and which the denominator as long as it is consistent with any standard to which it is

compared. Further, a ratio of 1/1 (or 1) is indicative of similarity, which as discussed above, is a valid indicator in the assay of the invention.

Applicants believe that the claims as presented are fully in compliance with 35 USC § 112, second paragraph. If a rejection is made under this section with respect to these claims, however, Applicants respectfully remind that Examiner that "it is incumbent on the Examiner to establish that one having ordinary skill in the art would not have been able to determine the scope of protection defined by the claim when read in light of the specification." *In re Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (POBAI 1989). The rejections presented in the Office Action in the parent case did not meet this standard.

In the parent case, the Examiner also rejected claims 18, 26 and 27 as anticipated by Niccoli et al. The Examiner asserted that Niccoli discloses "the claimed invention directed to a method of testing for a menopausal condition in a human." However, Niccoli does not disclose a test for menopausal condition but merely reports on test results using different antibodies directed to lutropin. In fact, the paper does not have anything to do with testing for menopausal condition and the data in Table 1 of the reference indicate that such a test would be unlikely to work for this purpose. A comparison of the results are the two post-menopausal women tested shows huge variability in the results, and for several tests results which are both above and below the values for normal women using the same assay kit.

Furthermore, the Examiner must consider all of the words, and thus all of the limitations in the claims when applying a reference. Step (a) of claim 18 reads

> obtaining a gonadotropin-containing sample from the human female individual, **wherein the gonadotropin present in the sample exists in a plurality of different forms, and wherein the form or forms in which the gonadotropin exists is different depending on whether or not a menopausal condition exists in the human female individual.**

The Examiner must indicate where in the reference this step, including the portion of this step set forth in bold above, is found in the reference if trhe rejeciton is to be maintained. Similarly, step(b) of claim 18 reads:

> (b) performing contemporaneous first and second assays on the sample obtained in step (a),
>
> **said first assay producing an indication of the gonadotropin that is independent of the whether the individual is pre-menopausal or post-menopausal,**
>
> **and said second assay producing an indication of the gonadotropin, wherein the indication produced in the second assay when the**

human female individual is pre-menopausal is different from the indication produced in the second assay when the human female individual is post-menopausal.

It is not sufficient that Niccoli performed multiple tests. All of the limitations of the claim must be met. There is no indication that any combination of kits tested by Niccoli would meet the limitations of this claim.

Finally, step (c) reads:

(c) comparing the results of the first and second assays **to determine the human female individual is pre-menopausal or post-menopausal.**

The mere fact that a comparison of assay results is done in Niccoli does not meet this limitation, because this comparison is not used as an indication of, and does not apparently provide an indication of the menopausal state of the individual tested.

Anticipation requires that each and every element of a claim is found in the single cited reference. The Examiner's failure to even mention substantial limitations in the rejected claims, including the reason that the method is performed, and the clear absence of any teaching of these limitations in the Niccoli reference make it apparent that this rejection is in error and should be withdrawn.

The Examiner used the same sort of selective reading of the claim to support the rejection of claims 18 and 19 as anticipated to Matikainen et al. in the parent case. This reference does not teach a method for assessing menopausal state. The tests performed do not meet the limitations of the claims. While two tests are performed, one is a test for bioactivity, while the other is a test for immunoreactivity. There is no indication that these tests discriminate in the manner indicated in the rejected claims, i.e., that one of the assays produces "an indication of the gonadotropin that is independent of the whether the individual is pre- or post-menopausal," and that the other assay produces "an indication of the gonadotropin that differs depending on whether the human female individual is pre-menopausal or post-menopausal." For these reasons, the rejection of claims 18 and 19 as anticipated by Matikainen should not be repeated.

Applicants note that claims 15 and 16 were indicated to be allowable in the parent case. In view of this and the arguments made herein, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

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